

AMENDMENTS TO THE CLAIMS

Claims 1-41 (Canceled).

42. (Currently amended) A solid composition comprising: (1) an immediate release layer comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of two pharmaceutically acceptable antioxidants; and (2) a sustained release layer comprising an effective amount of pseudoephedrine or a pharmaceutically acceptable salt thereof; and (3) a pharmaceutically acceptable sustained release agent; ~~and~~ wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2.0 % by weight.

43. (Previously presented) The solid composition of claim 42 wherein the two pharmaceutically acceptable antioxidants are edetate disodium and citric acid.

44. (Currently amended) A solid composition comprising: ~~(a1)~~ an immediate release first layer comprising an anti-allergic effective amount of desloratadine and at least one pharmaceutically acceptable excipient; ~~and (b2)~~ a sustained release second layer comprising an effective amount of pseudoephedrine or a pharmaceutically acceptable salt thereof; and (3) a pharmaceutically acceptable sustained release agent; wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2.0%.

45. (Currently amended) A solid composition comprising: (1) an immediate release first layer comprising about 2.5 mg of desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant; ~~and~~ (2) a sustained release second layer comprising about 120 mg of pseudoephedrine or a pharmaceutically acceptable salt thereof; ~~and~~ (3) a pharmaceutically acceptable excipient.

46. (Currently amended) The solid composition of claim 45 wherein the total amount of desloratadine degradation products is ~~no more than~~ less than or equal to about 2.0-% by weight.

47. (Currently amended) The solid composition of claim 45 wherein a desloratadine-protective amount of a pharmaceutically acceptable binder is present in the sustained release second layer.

48. (Previously presented) The solid composition of claim 45 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

49. (Currently amended) The solid composition comprising a first and a second layer wherein the first layer is an immediate release layer ~~comprising~~ wherein the ingredients comprise:

<u>INGREDIENT</u>	<u>mg/composition</u>
Desloratadine, micronized	5.0
Corn Starch NF/Ph.Eur.	36.0
Microcrystalline Cellulose NF/Ph.Eur./JP	140.7
Edetate Disodium	10.0
Citric Acid	2.0
Talc USP/Ph.Eur.	6.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	<u>0.30</u>
TOTAL	200.00

and wherein the second layer is a sustained release layer ~~comprising~~ wherein the ingredients comprise:

<u>INGREDIENT</u>	<u>mg/composition</u>
Pseudoephedrine Sulfate USP	120.0
Hydroxypropyl Methylcellulose 2208, 1000,00cps USP/Ph.Eur.	105.0
Microcrystalline Cellulose NF/Ph.Eur./JP	103.5
Hydroxypropyl Methylcellulose 2910	10.5
Edetate Disodium	3.5
Silicon Dioxide NF	5.0
Magnesium Stearate NF/Ph.Eur.JP(Non-Bovine)	<u>2.5</u>
TOTAL	350.0
TOTAL Tablet Weight	550.0

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

50. (Currently amended) A solid composition comprising a first layer and a second layer, wherein the first layer is an immediate release first layer ~~comprising~~ wherein the ingredients comprise:

<u>INGREDIENT</u>	<u>mg/composition</u>
Desloratadine, micronized	2.5
Corn Starch	18.0
Microcrystalline Cellulose	71.22
Edetate Disodium	5.0
Citric Acid	1.0
Talc	3.0
Dye FD+C Blue No. 2 Aluminium Lake	<u>0.28</u>
TOTAL	100.00

and wherein the second layer is ~~an~~ sustained release layer ~~comprising~~ wherein the ingredients comprise:

<u>INGREDIENT</u>	<u>mg/composition</u>
Pseudoephedrine Sulfate	120.0
Hydroxypropyl Methylcellulose 2208	105.0
Microcrystalline cellulose	103.5
Edetate Disodium	3.5
Hydroxypropyl Methylcellulose 2910	10.5
Silicon Dioxide	5.0
Magnesium stearate	<u>2.0</u>
TOTAL	350.0

and wherein total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

51. (Previously presented) The solid composition of claim 50 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37°C in about 45 minutes.

52. (Currently amended) A method of treating allergic ~~and/or~~ inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claims 42.

53. (Currently amended) A method of treating the signs and symptoms of nasal congestion associated with allergic and inflammatory conditions of the upper ~~and~~or lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 42.

54. (Currently amended) A method of treating the signs and symptoms of nasal congestion associated with allergic ~~and~~or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 44.

55. (Currently amended) A method of treating the signs and symptoms of nasal congestion associated with allergic ~~and~~or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 45.

56. (Currently amended) A method of treating the signs and symptoms of nasal congestion associated with allergic ~~and~~or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 50.

57. (Currently amended) A method of treating the signs and symptoms of urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 42.

58. (Currently amended) A method of treating the signs and symptoms of urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 44.

59. (Currently amended) A method of treating the signs and symptoms of urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 45.

60. (Currently amended) A method of treating the signs and symptoms of urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 49.

61. (Currently amended) A method of treating the signs and symptoms of urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 50.

62. (Currently amended) A method of treating the nasal and non-nasal symptoms of perennial ~~and/or~~ seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 42.

63. (Currently amended) A method of treating the nasal and non-nasal symptoms of perennial ~~and/or~~ seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 44.

64. (Currently amended) A method of treating the nasal and non-nasal symptoms of perennial ~~and/or~~ seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 45.

65. (Currently amended) A method of treating the nasal and non-nasal symptoms of perennial ~~and/or~~ seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 49.

66. (Currently amended) A method of treating the nasal and non-nasal symptoms of perennial ~~and/or~~ seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 50.

67. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 44.

68. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 45.

69. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 49.

70. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 50.

71. (New) A method of treating the signs and symptoms of nasal congestion associated with allergic and inflammatory conditions of the upper or lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 49.

72. (New) A solid composition comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant.

73. (New) The solid composition of claim 72 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

74. (New) The solid composition of claim 72 wherein total amount of desloratadine degradation products is less than or equal to about 2% by weight.

75. (New) The solid composition of claim 72 wherein about 0.1% to about 10% of at least one pharmaceutically acceptable antioxidant is present.

76. (New) The solid composition of claim 72 wherein the anti-allergic effective amount of desloratadine is about 2.5 mg.

77. (New) The solid composition of claim 72 wherein the anti-allergic effective amount of desloratadine is about 5 mg.

78. (New) The solid composition of claim 72 wherein two pharmaceutically acceptable antioxidants are present.

79. (New) A solid composition comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

80. (New) The solid composition of claim 79 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

81. (New) The solid composition of claim 79 wherein about 0.1% to about 10% of at least one pharmaceutically acceptable antioxidant is present.

82. (New) The solid composition of claim 79 wherein the anti-allergic effective amount of desloratadine is about 2.5 mg.

83. (New) The solid composition of claim 79 wherein the anti-allergic effective amount of desloratadine is about 5 mg.

84. (New) The solid composition of claim 79 wherein two pharmaceutically acceptable antioxidants are present.

85. (New) A solid composition comprising an anti-allergic effective amount of desloratadine and at least one pharmaceutically acceptable excipient, wherein total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight, and wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

86. (New) The solid composition of claim 85 wherein total amount of desloratadine degradation products in the solid composition is less than or equal to about 1.5% by weight.

87. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	2.5
Corn Starch	11.0
Dibasic Calcium Phosphate Dihydrate	53.0
Microcrystalline Cellulose	30.22
Talc	3.0
Dye FD + C Blue No. 2 Aluminium Lake	0.28
TOTAL	100.00

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

88. (New) The solid composition of claim 87 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

89. (New) A solid composition comprising about 5 mg of desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant, wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

90. (New) The solid composition of claim 89 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

91. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	5.0
Corn Starch NF/Ph. Eur.	11.0
Dibasic Calcium Phosphate Dihydrate USP/Ph. Eur.	53.0
Microcrystalline Cellulose NF/Ph. Eur./JP	27.72

Talc USP/PH. Eur	3.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.28
TOTAL	100.00

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

92. (New) The solid composition of claim 91 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCL solution at 37° C in about 45 minutes

93. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	5.0
Corn Starch NF/Ph. Eur.	36.0
Microcrystalline Cellulose NF/Ph. Eur./JP	132.7
Edetate Disodium USP	10.0
Citric Acid Anhydrous, USP	10.0
Stearic Acid, NF.	6.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.3
TOTAL	200.0

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

94. (New) The solid composition of claim 93 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

95. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	2.5
Corn Starch NF/Ph. Eur.	18.0
Microcrystalline Cellulose NF/Ph. Eur./JP	66.35
Edetate Disodium	5.0
Citric Acid	5.0

Stearic Acid USP/Ph. Eur.	3.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.15
TOTAL	100.00

and wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

96. (New) The solid composition of claim 95 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

97. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 72.

98. (New) A method of treating urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 72.

99. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 72.

100. (New) A solid composition comprising an anti-allergic effective amount of desloratadine and a desloratadine-protective amount of two pharmaceutically acceptable antioxidants, wherein total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

101. (New) The solid composition of claim 100 wherein the two pharmaceutically acceptable antioxidants are edetate disodium and citric acid.

102. (New) A solid composition comprising an anti-allergic effective amount of desloratadine and at least one pharmaceutically acceptable excipient, wherein total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

103. (New) A solid composition comprising about 2.5 mg desloratadine and a desloratadine-protective amount of at least one pharmaceutically acceptable antioxidant.

104. (New) The solid composition of claim 103 wherein the total amount of desloratadine degradation products in the solid composition is no more than about 2% by weight.

105. (New) The solid composition of claim 103 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

106. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	5.0
Corn Starch NF/Ph. Eur.	36.0
Microcrystalline Cellulose NF/Ph. Eur./JP	140.7
Edetate Disodium	10.0
Citric Acid	2.0
Talc NF/Ph. Eur.	6.0
Dye FD&C Blue No. 2 Aluminium Lake 5627	0.3
TOTAL	200.0

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

107. (New) The solid composition of claim 106 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

108. (New) A solid composition whose ingredients comprise:

INGREDIENT	mg/composition
Desloratadine, micronized	2.5
Corn Starch NF/Ph. Eur.	18.0
Microcrystalline Cellulose NF/Ph. Eur./JP	71.22
Edetate Disodium	5.0
Citric Acid	1.0
Talc NF/Ph. Eur.	3.0

Dye FD&C Blue No. 2 Aluminium Lake 5627	0.28
TOTAL	100.00

wherein the total amount of desloratadine degradation products in the solid composition is less than or equal to about 2% by weight.

109. (New) The solid composition of claim 108 wherein at least about 80% of the desloratadine dissolves in a 0.1N HCl solution at 37° C in about 45 minutes.

110. (New) A method of treating allergic or inflammatory conditions of the upper and lower airway passages and skin which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 100.

111. (New) A method of treating the urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 100.

112. (New) A method of treating the urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 102.

113. (New) A method of treating urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 103.

114. (New) A method of treating urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 106.

115. (New) A method of treating urticaria which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 108.

116. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 100.

117. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 102.

118. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 103.

119. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 106.

120. (New) A method of treating the nasal and non-nasal symptoms of perennial or seasonal allergic rhinitis which comprises administering to a patient in need of such treating an effective amount of the solid composition of claim 108.